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TO RUEHC/SECSTATE WASHDC 7650
INFO RUEHRI/AMCONSUL RIO DE JANEIRO 3554
RUEHRG/AMCONSUL RECIFE 6019
RUEHSO/AMCONSUL SAO PAULO 8864
RUEHBU/AMEMBASSY BUENOS AIRES 4478
RUEHAC/AMEMBASSY ASUNCION 5845
RUEHMN/AMEMBASSY MONTEVIDEO 6653
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UNCLAS SECTION 01 OF 02 BRASILIA 002606

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STATE PASS USTR:SCRONIN/MSULLIVAN
USDOC FOR 3134/USFCS/OIO/WH/SHUPKA
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STATE FOR EB/TPP/BTA and WHA

E.O. 12958: N/A
TAGS: ETRD ECON BR
SUBJECT: BRAZIL - REGULATORY AGENCY FORGING AHEAD WITH NEW REQUIREMENTS FOR MEDICAL DEVICE REGISTRATION

REF: BRASILIA 2589

¶1. (SBU) Summary: Emboffs met December 12 with representatives of Brazil's National Sanitary Vigilance Agency (ANVISA, an FDA-like agency) to clarify the scope of new requirements for commercial and pricing information for approval of medical device sales and urge that the GoB take into account industry concerns over the implementation of the measure (reftel). Economic and Regulatory Issues Department Director Pedro Bernardo and International Relations Director Rogerio Ferreira argued that the new regulation was merely the application to medical devices of the requirements for provision of commercial information as part of the ANVISA licensing process that were introduced in 2003 by law 10742; these requirements already applied to pharmaceuticals. Bernardo stated that both the new regulations and law 10742 only require provision of pricing data for licensing approval and do not give ANVISA any power over these pricing decisions. Bernardo stated that the regulations apply equally to Brazilian and imported products. He dismissed industry concerns that anti-trust considerations might prohibit provision of pricing data. Bernardo assured Emboffs that ANVISA would protect companies' proprietary commercial strategy information, but would share with other GoB agencies the pricing information provided. End Summary.

¶2. (U) Emboffs met, at our request, with ANVISA reps Bernardo and Ferreira to urge that industry concerns over a new regulation (185/2006) be taken into account, as well as to clarify the regulation's provisions. In order to obtain ANVISA approval for registering or re-registering medical devices, the new regulation requires companies to provide commercial/pricing data on the product. Companies are required to provide 1) the intended price for the product on the Brazilian market; 2) the company's estimates of the number of patients that would use the product; 3) factory price and distribution margins; 4) expected sales and marketing expenses; 5) a list of substitute or similar products and their prices; and, 6) if the product is sold in any of ten specified countries (Portugal, France, U.S., Germany, Australia, Canada, Spain, Italy, Japan and the United Kingdom) then price at which it sold in those markets must be submitted, along with supporting documentation.

¶3. (U) Bernardo argued that the new regulation was simply the next step in the process of regulating law 10742 of 2003. This law, he said, requires that commercial and pricing data be provided in order to register pharmaceuticals and medical devices. ANVISA began the process by requiring the same information for pharmaceuticals,

which, he affirmed, the companies had been providing without incident. It simply took ANVISA some time to grapple with how to approach the less standardized medical devices sector. Bernardo said ANVISA and the Ministry of Health had held extensive discussions with government institutions, health insurance companies and the industry to understand the market of medical devices. After talking to industry and government, in December 2005, ANVISA put the resolution 185/2006 for public comment until February 2006. In November 2006 the resolution was passed and it goes into effect on December 13.

¶4. (U) According to Bernardo, ANVISA consultations with other institutions pointed up a number of information problems in the sector. The federal agencies responsible for the federal health system (SUS) and private health insurance companies stated that the costs of medical devices have been a large factor in increasing the costs of their operations. There also was considerable confusion over pricing of devices and which devices are substitutes, Bernardo affirmed. He alleged that they found in one case that the same basic product has sixty different prices on the market from different providers.

¶5. (U) ANVISA and Ministry of Health decided to apply the pricing data requirements to about 5 percent of the medical devices on the market, according to Bernardo. The products chosen are the ones that have shown consistent price increases over the last five years for SUS and health insurers. Health insurers and government are responsible for 80 percent of the demand for these products, Bernardo stated. ANVISA stated that current information is asymmetric, making it difficult for customs and ANVISA to classify products. Government also faces difficulties in correctly taxing these products, Bernardo alleged. The products listed are for: cardiovascular procedures; orthopedic procedures; clinical analysis



(laboratory procedures); kidney therapy; ophthalmological procedures; hemotherapy procedures; and otorhinolaryngologist procedures.

¶6. (U) Bernardo stated that ANVISA will use the information received to put together a database and create a standards nomenclature to simplify the process of customs processing and product registration with ANVISA. Government will also use the information to correctly tax the products. ANVISA will also use the information collected to provide price and quality comparisons, allowing government bodies responsible for procurement to make better decisions. Bernardo affirmed that pricing information is public information and will be released to entities with access to its database, but companies' proprietary marketing strategy information would be kept confidential.

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¶7. (SBU) Emboffs raised a series of concerns that industry has put forward about the measure, including: 1) the difficulty of gathering much of the information requested; 2) anti-trust considerations as the regulation requires companies to provide pricing data on competing products; 3) that the regulation would serve as an additional obstacle to getting devices licensed, and thus would reduce Brazilian consumers' access to the latest innovative technologies; 4) the impression that this regulation creates that Brazil is headed towards price controls for these devices; and, 5) whether the regulation applies equally to imported and domestic devices.

¶8. (SBU) In dismissing concerns over anti-trust law or that industry would have difficulty providing the data, Bernardo argued that the pharmaceutical industry has been providing similar data without incident for over a year. The new requirements were not onerous, he affirmed, and thus would not limit new product registrations. Moreover, the law upon which the new regulation is based does not allow for price controls on medical devices. It would take new legislation passed by Congress to introduce such controls. Finally, the regulation applies equally to imported and domestic products, so there is no national treatment issue, Bernardo affirmed.

¶9. (SBU) Emboffs requested an advance copy of the form that companies will have to fill out. The form is now also available on the ANVISA internet site (www.anvisa.gov.br), along with an instruction manual explaining how to fill out the form. Companies may be required to submit supporting documentation in some cases. After the resolution goes into effect on December 13, there will be a sixty-day phase in period for companies to begin complying with the resolution. Bernardo implied that, were there clearly serious and justified difficulties in meeting the new requirements during this period, ANVISA might tweak the procedures or requirements. But it would be forging ahead with implementation, he said.

10 (SBU) Comment: In our own review of the text of law 10742, upon which Bernardo said this measure was based, we did not find specific mention medical devices (as opposed to pharmaceuticals). That does not necessarily mean that the new regulation is without legal basis in other legislation. It does suggest, however, that ANVISA's ultimate intent is controlling costs in the public health system, as law 10742 was clearly aimed at reducing pharmaceutical prices.

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